

**Remarks/Arguments**

Claims 1-22 are pending in the Application.

Claims 1-4, 6, and 8-13 stand rejected.

Claims 4-9 and 13-22 are being canceled herein.

Claims 1-3 and 10-12 are amended herein.

**I. EXAMINER INTERVIEW**

On October 26, 2004, counsel for Applicant (Ross Garsson and Melissa Schwaller) had a telephone interview with the Examiner to discuss the Application and the Final Office Action. Applicant and its counsel appreciate the opportunity to have this discussion and wish to thank the Examiner for the interview.

**II. REJECTIONS UNDER 35 U.S.C. § 112, ¶ 1**

In the Final Office Action, the Patent Examiner rejected Claims 1-4, 6 and 8-13 under 35 U.S.C. §112, ¶ 1, as not reasonably providing enablement of various portions of the claims. Final Office Action, at 3.

In response to this Final Office Action and the Examiner Interview held October 26, 2004, Applicant has canceled Claims 4, 6, 8-9 and 13. (Applicant has further canceled Claims 5, 7 and 14-22 were previously withdrawn, with traverse). Applicant has amended Claims 1-3 and 10-12 herein. The amendment to Claims 1-3 and 10-12 were modified consistent with what was discussed during the Examiner Interview, particularly in view of the materials Applicant has submitted herewith.

During the interview, the Examiner indicated that Applicant provide material supporting the claimed operability of the invention regarding other diseases that use the same signaling pathway as Crohn's disease and other substances that bind TNF-alpha in such a way as to stop TNF-alpha from activating TNF Receptor II. Accordingly, Applicant has attached herewith an Affidavit of Stefan Schreiber, the first-named inventor, reflecting such requested materials. In

support of the Affidavit of Stefan Schreiber, copies of articles and abstracts are attached in a Supplemental Information Disclosure Statement.

Accordingly, Applicant respectfully requests the Examiner withdraw its rejection of the claims under 35 U.S.C. §112, ¶ 1.

**III. CONCLUSION**

As Applicant has amended this application to amend or cancel the rejected claims, Applicant believes that this application should proceed to allowance. However, in order to ensure that this Application is not inadvertently abandoned, Applicant has, as noted above, concurrently filed a Request for Continued Examination.

Applicant believes that no other fees are due; however, the Director is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C.

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at 214.745.5633.

Respectfully submitted,

WINSTEAD SECHREST & MINICK P.C.

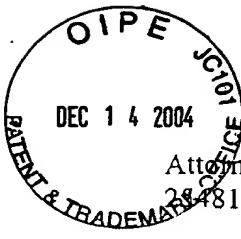
Attorneys for Applicant

Date: December 14, 2004

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25481-P001US 12/10/2004



Attorney Docket No.  
28481-P001US

PATENT  
Serial No. 09/902,176

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Schreiber, et al.  
Serial No: 09/902,176  
Filing Date: July 10, 2001  
Confirmation No: 7507  
Examiner: Sakelaris, Sally A.  
Art Unit: 1634  
Title: DIAGNOSTIC USE OF POLYMORPHISMS IN THE GENE CODING FOR  
THE TNF RECEPTOR II AND METHOD FOR DETECTING  
NON-RESPONDERS TO ANTI-TNF THERAPY

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

EINGEGANGEN

- 9. Dez. 2004

DR. KLUNKER  
DR. SCHMITT • NILSON • HIRSCH

AFFIDAVIT OF STEFAN SCHREIBER

BEFORE ME, the undersigned authority on this day personally appeared Dr. STEFAN SCHREIBER, who made the following written verification:

1. I am co-inventor and co-applicant, along with Silvia Mascheretti and Jochen Hampe, with respects to the above styled patent application (collectively hereinafter the "co-inventors").

2. My education is as follows:

Personal Data:

Born: June 25, 1962; Berlin

Academic education:

1981 Studies of Medicine and Chemistry  
1983-1987 Experimental thesis in muscular physiology  
"Temperature dependency of post-vibration  
tension recovery in skinned and intact smooth  
muscle fibres". Advisors: Professor Dr. E. Rumberger and Professor Dr.  
U. Peiper

1986 Final exam in Medicine  
1988 Doctor of Medicine, "magna cum laude"

**Positions Held:**

April-1986 to May 1987	"PJ" (equivalent to medical internship)
May 1987	Approbation
May/June 1987	Duplex-Sonography and Angiodynography at the University of Washington, Seattle (Dr. D.E. Strandness, Jr.)
July 1987 to Sept. 1988	Assistant at the Hospital of the University of Hamburg Medical Department (Director: Prof. Dr. H. Greten)
October 1988 to Jan. 1990	Research Associate, Washington University School of Medicine, Division of Gastroenterology
February 1990 to May 1991	Research Associate, University of Pennsylvania School of Medicine, Gastrointestinal Section
June 1991 Nov. 1994	Assistant at the Hospital of the University of Hamburg Medical Department (Director: Prof. Dr. H. Greten)
Dec. 1994- Jan. 1998	Faculty at the Charité University Hospital (Humboldt University), IVth Medical Department  (Director: Prof. Dr. H. Lochs)
1996	Completion of "Privat-Dozent" Thesis and Lecturer in Internal Medicine at the Charité University Hospital
Feb. 1998- Jan. 2004	Frederik Paulsen Professor for Medicine and Gastroenterology Christian-Albrechts University in Kiel
From Jan. 2004	Professor for Clinical Molecular Biology at the Christian-Albrechts University Kiel

Attorney Docket No.  
25481-P001US

PATENT  
Serial No. 09/902,176

- 5       3. Other diseases that use the same signaling pathway as Crohn's disease include, but are not limited to,
  - a. Rheumatoid arthritis (Elliot et al., 1994, Lancet; Fabris et al., 2002, J Rheumatol)
  - b. Psoriasis (Ogilvie et al., 2001, Br J Derm)
  - c. Sarcoidosis (Yee et al., 2001, Ann Intern Med)
  - d. SLE (Aringer et al., 2004, Arthritis and Rheumatism)
  - e. Colonic carcinoma (Becker et al., 2004, Immunity; Rose-John & Neurath, 2004, Immunity; Atreya et al., 2000, Nat Med)
- 15      4. Other substances that bind TNF-alpha in such a way as to stop TNF-alpha from activating TNF Receptor II include, but are not limited to,
  - a. Onercept, soluble recombinant PEGylated TNFR1 (Rutgeerts et al., 2003, Alim Pharm Ther)
  - b. Adalimumab , humanized anti TNF antibody (den Broeder et al., 2002, Ann Rheum Dis)
  - c. CDP870, humanized PEGylated anti TNF antibody fragment (Choy et al., 2002, Rheumatology (Oxford))
  - 25      d. CDP571, engineered human monoclonal anti TNF antibody (Sandborn et al., 2001, Gastroenterology)
- 30      5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that any willful false statements may jeopardize the validity of the application or any patent issued thereon.

Attorney Docket No.  
25481-P001US

PATENT  
Serial No. 09/902,176

Further Affiant sayeth not.

*Stefan Schreiber*

STEFAN SCHREIBER

Urkundenrolle Nr. 295/2004

Dr. Stefan Schreiber appeared before me and personally signed on the 7 day of

December, 2004.

geboren am 25.06.1962, Moltkestr. 77, 24105 Kiel, ausgewiesen durch Reisepaß  
Dr. Stefan Schreiber ist vor mir erschienen und hat eigenhändig unterzeichnet am

7. Dezember, 2004.



*Brod* dr. Notar

Notary Public Signature  
Unterschrift des Notars

Kostenberechnung:

Geschäftswert: 5.000,00 EUR

5/20 Gebühr gem. §§ 141, 32, 45 KostO  
16 % Umsatzsteuer

10,50 EUR
1,68 EUR
<u>12,18 EUR</u>

*Brod*

Notar

Dallas 140589691  
25481-P001US 11/1/2004

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